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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,505	08/23/2006	Toshikazu Nakamura	2005_1415A	9976

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,505	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 14-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/1/07, 6/2/2006, 9/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 14-20 have been newly added.

Election/Restrictions

Applicant's election of Group 3, claims 10 and 14-20, in the reply filed on 5/21/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-9 and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/21/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering SEQ ID NOS: 1 and 2 to treat bronchial asthma by suppressing airway inflammation, does not reasonably provide enablement for all methods of treatment embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

SEQ ID NO: 1 is the full length sequence for human HGF. SEQ ID NO: 2 is a known naturally occurring variant of human HGF. It possesses a five amino acid deletion in the first kringle domain.

The examples administer the full length protein to mice and show suppression of airway inflammation in a murine model of asthma. However, there is no evidence of record nor reason to believe that administration of HGF will **prevent** the occurrence of asthma or airway inflammation. (See claims 10, 14-15, 17, and 19.) The prior art of record and specification do not demonstrate a prophylactic effect for HGF. The prior art of record and specification do no disclose prevention of asthma by any therapeutic agent.

While the paragraph bridging pages 3-4 of the specification defines HGF as a heterodimeric protein composed of an α chain and a β chain consisting of an N-terminal hairpin domain and four kringle domains, it is not clear that claims 10 and 16-20 are limited to this structure. Claims 10 and 16 recite HGF in the absence of any structural features. Claim 14 includes partial peptides as well as variant sequences in reciting "**an** amino acid sequence **substantially identical to an** amino acid sequence **represented by** SEQ ID NO: 1 or 2" (emphasis added). Claim 15 includes subsequences of SEQ ID NO: 2 in reciting "**an** amino acid sequence **represented by** SEQ ID NO: 2" (emphasis added). Other than the sequences of SEQ ID NOS: 1 and 2, the specification does not identify any variant sequences or partial peptides that would be useful in a method of preventing or treating asthma by suppressing airway inflammation. The specification does not disclose any variant sequences, partial peptides, or substantially identical amino acid sequences that possess this activity. The specification does not provide guidance as to those other HGF proteins that would have been expected to possess this

activity. It is not considered to be so predictable that other HGF proteins within the claims could have been identified without undue experimentation based on the instant disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The paragraph bridging pages 3-4 of the specification defines HGF as a heterodimeric protein composed of an α chain and a β chain consisting of an N-terminal hairpin domain and four kringle domains. Claim 10 recites HGF in the absence of any structural features. It is unclear if claim 10 requires the features recited on pages 3-4.

Dependent claims 14-15 are confusing because they do not clearly require these structures. SEQ ID NO: 2 contains a five amino acid deletion in the first kringle domain. Claim 14 includes partial peptides as well as variant sequences in reciting "**an** amino acid sequence **substantially identical to an** amino acid sequence **represented by** SEQ ID NO: 1 or 2" (emphasis added). Claim 15 includes subsequences of SEQ ID NO: 2 in reciting "**an** amino acid sequence **represented by** SEQ ID NO: 2" (emphasis added).

Claims 14-15 do not appear to be properly dependent as they do not contain all of the limitations of the independent claim in view of the definition on pages 3-4. Clarification is requested.

With respect to claim 14, it is not known what level of identity would meet the limitation of "substantially identical."

Conclusion

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ito et al. (2005) and Ito et al. (2008) are not prior art against the instant claims but address the role of HGF in treating bronchial asthma.

Schwartz (U.S. Patent No. 7,074,764) is prior art against the instant claims. The patent discloses intravenously administering HGF to rats in pharmaceutically acceptable carriers in the amounts claimed for treating inflammation and reducing cytokine inflammatory mediators. The patent does not exemplify treating humans and does not disclose treating asthma.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa